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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/786,309	06/06/01	MISHINA	M 55573

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EXAMINER	
NGUYEN, I	
ART UNIT	**PAPER NUMBER**
1635	7

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/786,309	MISHINA ET AL.	
	Examiner	Art Unit	
	Lauren Nguyen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-7 provides for the use of a psoralen derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> *A person shall be entitled to a patent unless –*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Glazer *et al.* (WO 95/01364).

Claims 1 and 2 are drawn to a mutagenesis method of a gene of a vertebrate animal by using a psoralen derivatice or trimethylpsoralen wherein the mutated region contains a pyrimidine base. Claim 6 is drawn to a method for preparing the gene mutated by the method of claims 1 or 2. Claim 7 is drawn to a method for analyzing the function of a gene of a vertebrate animal, comprising inducing mutagenesis in a gene region containing a pyrimidine base by using a psoralen derivative and expressing the mutated gene and examining the correlation thereof.

Glazer *et al.* discloses a mutagenic oligonucleotide comprising trimethylpsoralen (refer to Fig.1 and/or the description of Figure 1 on p. 5, lines8-) and methods for use thereof wherein the oligonucleotide is chemically modified to incorpoate a mutagen with a specific DNA segment of a target DNA molecule (see abstract). Such mutation produced from the disclosed method activates, inactivates, or alters the activity and function of the target molecule (see abstract). Glazer *et al.* discloses one of the gene targets using the disclosed method can be a human oncogene suppressor gene (p. 10, lines 1-). Additionally, Glazer *et al.* also discloses the base composition of the target genes to comprise of polypyrimidines (p. 10, line 10-). Furthermore, Glazer *et al.* discloses in Example 1, on p. 15, lines 33-, the use of the disclosed method on the supF gene and the analysis of the supF activity following treatment of the psoralen derivative.

Therefore, the invention of the above claims is anticipated by Glazer *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stuart *et al.* (Development, Vol. 107, p. 577-584, 1990) in view of Glazer *et al.* (WO 95/01364).

Claim 3 is drawn to the mutagenesis method of a gene of a vertebrate animal as recited in claim 1 wherein the vertebrate animal is zebrafish.

Glazer *et al.* teaches a mutagenic oligonucleotide comprising trimethylpsoralen and methods for use thereof wherein the oligonucleotide is chemically modified to incorporate a mutagen with a specific DNA segment of a target DNA molecule (see item #1 above in this Office Action).

Stuart *et al.* teaches the use of zebrafish as simple vertebrate animal models in transgenic studies since the zebrafish is capable of exhibiting reproducible, tissue-specific patterns of expression which would facilitate mechanistic studies of developmentall regulated gene expression of the transgene. (p. 577, paragraph 1). Moreover, Stuart *et al.* teaches that the production, maintenance and analysis of mutant zebrafish cell lines are possible because the zebrafish exhibits a relatively short 3-4 months generation time. (p. 577, paragraph 2).

The ordinary skilled artisan, guided by the combined teachings of Glazer *et al.* and Stuart *et al.*, would have been motivated to use the method of claim 1 with a gene of a zebrafish since Glazer *et al.* teaches a method of using a mutagenic oligonucleotide comprising

trimethylpsoralen in targeting specific genes and Stuart *et al.* teaches the advantage of using zebrafish cells in the production, maintenance and analysis of mutant cell lines which carry mutated, transgenic genomes. Said advantages taught by Stuart *et al.* include reproducible, tissue-specific patterns of gene expression and relatively short generation times, for instance.

It would have been obvious to the ordinary skilled artisan to combine the teachings of Glazer *et al.* and Stuart *et al.* and use the method of claim 1 with a gene of a zebrafish because Glazer *et al.* teaches a mutagenesis method comprising trimethylpsoralen in targeting specific genes and Stuart *et al.* teaches the advantages of using zebrafish cells for the production, maintenance and analysis of mutant cell lines which carry mutated, transgenic genomes.

The ordinary skilled artisan would have had a reasonable expectation of success in using the method of claim 1 with a gene of a zebrafish since Glazer *et al.* teaches a mutagenesis method and steps therein comprising trimethylpsoralen in targeting specific genes and Stuart *et al.* teaches the advantages of using zebrafish cells for the production, maintenance and analysis of mutant cell lines which carry mutated, transgenic genomes.

Therefore, the invention of the above claim would have been *prima facie* obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. Claim 2 recites "...the psoralen derivative is trimethylpsoralen." In Figure 1 of the specification, methyl substituients are positioned in designated positions on the psoralen parental structure listed as TMP. The recitation of trimethylpsoralen fails to recites the metes and bounds of the claimed limitation; please claim the exact subject matter which applicant regards as the invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being unclear and indefinite. Claim 4 recites "...wherein the gene is a germ cell gene." The definition and embodiment of a "germ cell gene" is unclear to the Examiner since said recitation was not defined in the specification or the claims as originally filed.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being unclear and indefinite for lack of antecedent basis. Claim 5 recites "...wherein the mutated region is a region..." The recitation of "mutated region" does not appear in dependent claims 1-4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lauren Nguyen, Ph.D.
August 23, 2001

SEAN McGARRY
PRIMARY EXAMINER